

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON**

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-md-02327 MDL No. 2327
THIS DOCUMENT RELATES TO: <i>Carolyn Lewis, et al. v. Johnson & Johnson, et al.</i> Case No. 2:12-cv-04301	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

**MEMORANDUM IN SUPPORT OF DEFENDANTS ETHICON, INC. AND JOHNSON &
JOHNSON'S MOTION FOR JUDGMENT AS A MATTER OF LAW**

INTRODUCTION

Plaintiff's sole remaining theory of liability, for defective design, should not be submitted to the jury. As Ethicon¹ has already explained at length, she has failed to present sufficient evidence on any element of that theory. In addition, Plaintiff's claim is untimely because her cause of action accrued no later than January or February 2010, yet she did not file suit until July 25, 2012, months beyond the applicable two-year limitations period. In any event, Plaintiff is not entitled to punitive damages. For these and other reasons, Ethicon respectfully moves the Court for judgment as a matter of law. Plaintiff has not offered a "legally sufficient evidentiary basis" for her claims, Fed. R. Civ. P. 50(a)(1), and so the "evidence presented supports only one reasonable conclusion as to the verdict." *Bank of Montreal v. Signet Bank*, 193 F.3d 818, 831 (4th Cir. 1999). Ethicon reserves the right to supplement this Motion based on additional evidence adduced at trial.

LEGAL STANDARD

Even when "view[ing] the evidence in the light most favorable" to Plaintiff, and "draw[ing] all reasonable inferences in [her] favor without weighing the evidence or assessing the witnesses' credibility," Plaintiff's proof is deficient. *Sawyer v. Asbury*, 861 F. Supp. 2d 737, 745 (S.D. W. Va. 2012) (quoting *Baynard v. Malone*, 268 F.3d 228, 234-35 (4th Cir. 2001)). Although Ethicon submits it is entitled to judgment on all issues, a Rule 50(a) motion can be granted on all issues, or on any issue where "a reasonable jury would not have a legally sufficient evidentiary basis to find for the [non-moving] party on that issue." Fed. R. Civ. P. 50(a); *see also Int'l Ground Transp., Inc. v. Mayor of Ocean City*, 475 F.3d 214, 218-19 (4th Cir. 2007).²

¹ "Ethicon" refers to both Defendants Ethicon, Inc. and Johnson & Johnson.

² Ethicon has included in this Motion grounds for judgment that the Court declined to adopt in its summary judgment rulings. Ethicon acknowledges the Court's rulings and respectfully submits these grounds for judgment to preserve them in the event of any appeal.

ARGUMENT

I. No Reasonable Juror Could Find in Favor of Plaintiff on Any Element of Her Design-Defect Claim.

A. Ethicon Is Entitled to Judgment on Plaintiff's Strict-Liability Design-Defect Claim.

For the reasons explained in Ethicon's trial brief [Doc. 286] and supplemental brief on specific causation [Doc. 288], Plaintiff has failed to present evidence that would enable a reasonable juror to find in her favor that: (1) the TVT is unreasonably dangerous as designed; (2) there was a safer, feasible, and equally efficacious alternative design to the TVT that was available at the time of Plaintiff's implantation in 2009 and would have significantly reduced the risk of her alleged injury; or (3) any alleged defect in the TVT caused Plaintiff to sustain any injuries. *See, e.g., Smith v. Louisville Ladder Corp.*, 237 F.3d 515, 519-20 (5th Cir. 2001); *Dyer v. Danek Med., Inc.*, 115 F. Supp. 2d 732, 738-39 (N.D. Tex. 2000). Accordingly, Ethicon is entitled to judgment as a matter of law.

B. Ethicon Is Entitled to Judgment on Plaintiff's Negligent-Design Claim.

Plaintiff's failure to present sufficient evidence of a design defect or a safer alternative design as defined by Texas law is fatal to her negligent-design claim just as it is to her strict-liability claim. *See, e.g., Gerber v. Hoffman-La Roche Inc.*, 392 F. Supp. 2d 907, 922 (S.D. Tex. 2005) (granting judgment on negligence claim where strict-liability design-defect claim failed for failure to show safer alternative design); *Brockert v. Wyeth Pharms., Inc.*, 287 S.W.3d 760, 771 (Tex. App.—Houston 2009) (plaintiff's "failure to raise a fact issue concerning a safer alternative design disposes of all of her design-defect claims, including her negligent-design-defect claim"); *Ford Motor Co. v. Miles*, 141 S.W.3d 309, 316-17 (Tex. App.—Dallas 2004, pet. denied) ("[B]oth negligence and strict liability for defective design require proof of a defect in the product."). So too does Plaintiff's failure to prove causation doom her negligence and strict-

liability claims alike, since “[p]roximate causation subsumes within it the concept of producing cause. If a defect is not a producing cause of an injury, it cannot constitute, as a matter of law, a proximate cause.” *Miles*, 141 S.W.3d 309, 318 (Tex. App.—Dallas 2004, pet. denied); *see also Hyundai Motor Co. v. Rodriguez*, 995 S.W.2d 661, 667 (Tex. 1999) (producing cause standard for strict liability claims is a “lesser finding” than the proximate cause required to sustain a negligence claim).

Plaintiff’s negligence theory is indistinguishable from her strict liability theory in that both are premised on the notion that a defect in the design of the TVT caused chronic pain, dyspareunia, and voiding dysfunction. Because there is no defective design, Ethicon cannot be subject to liability for negligence. As one Texas court explained:

it is not logical for a manufacturer to be held liable for failing to exercise ordinary care when producing a product that is not defective because . . . even if the manufacturer was somehow negligent in the design or production of the product, that negligence cannot have caused the plaintiff’s injury because the negligence did not render the product “unreasonably dangerous.”

Ford, 141 S.W.3d at 315; *accord* 1 David G. Owen, M. Stuart Madden & Mary J. Davis, MADDEN & OWEN ON PRODUCTS LIABILITY § 2:1 (3d ed. 2000) (“[I]t is perfectly clear that, except in certain limited contexts [involving negligent entrustment or misrepresentation], it can hardly be negligent to make and sell a product that is good.”).

To the extent that Plaintiff premises her negligence claim on a theory of inadequate testing, she still has failed to present sufficient evidence of specific causation to submit this case to the jury. That claim too is subsumed within the strict-liability claim. See *Mata v. Energy Absorption Sys.*, 2011 Tex. App. LEXIS 2425 (Tex. App. 2011) (“The Matas’ claims based on the three remaining assertions . . . for negligent design, negligent testing, and failing to test are premised upon the existence of a design defect. These claims fail because there is no evidence that a design defect was a producing cause of Mata’s injuries.”)

II. Plaintiff's Claim is Untimely.

Plaintiff commenced suit on July 25, 2012, but this falls well beyond the applicable two-year limitations period since her claim accrued. *See* TEX. CIV. PRAC. & REM. CODE § 16.003(a) (“a person must bring suit for . . . personal injury . . . not later than two years after the day the cause of action accrues”).³ Because Plaintiff’s cause of action accrued when she “discover[ed], or through the exercise of reasonable care and diligence should have discovered, the nature of the injury,” *Porterfield v. Ethicon, Inc.*, 183 F.3d 464, 467 (5th Cir. 1999), the question for the Court is whether a reasonable person would have begun to make inquiry before July 25, 2010. The answer is yes: any reasonable person who, like Plaintiff, enjoyed a “very active sex life” prior to her November 2009 implantation but allegedly experienced painful sex (which she attributed to the TVT implantation) weeks after her surgeon told her she was “good to go” and that she should seek medical attention if she had “any problems,” would have inquired into her legal rights and discovered her potential claim several months before July 25, 2010.

Under Texas law, a cause of action ordinarily accrues as soon as the wrong is completed and a lawsuit can be commenced, “even if the party is unaware of the wrong.” *Porterfield*, 183 F.3d at 467. But where an injury is “inherently undiscoverable,” Texas courts have applied the discovery rule to delay the accrual until a person discovers, or through reasonable diligence should have discovered, the nature of her injury. *Id.*; *Brandau v. Howmedica Osteonics Corp.*, 439 F. App’x 317, 319, 322 (5th Cir. 2011) (noting Texas requires “nature of the injury must be

³ Ethicon submits that it is entitled to judgment as a matter of law based on the statute of limitations based on Plaintiff’s trial testimony on cross examination that she experienced pain with sex in January 2010 and again several weeks later, which she attributed to the TVT implantation, and in late 2010 saw a lawyer advertisement regarding supposed complications of mesh slings. While Ethicon did not address this issue in the proposed joint pretrial order, the basis of this ground is testimony elicited after that submission and, in any event, Plaintiff has not suffered any cognizable prejudice because she was able to, and in fact did, engage in redirect examination and subsequently called her husband to testify.

inherently undiscoverable and the injury itself must be objectively verifiable”); *Bell v. Showa Denko, et al.*, 899 S.W.2d 749, 754 (Tex. App. 1995).

Accrual does not require a person to have “actual knowledge of the particulars of a cause of action,” but merely “knowledge of facts which would cause a reasonable person to diligently make inquiry *to determine his or her legal rights.*” *Bell*, 899 S.W.2d at 754 (emphasis added). This passage, the Fifth Circuit has explained, “presumes that the discovery period begins *before* a plaintiff has actionable knowledge or, as the [plaintiffs] describe it, knowledge of ‘sufficient facts that actually connect the injury and the tortfeasor.’” *Vaught v. Showa Denko K.K.*, 1997 U.S. App. LEXIS 12786, at *13 (5th Cir. 1997). In other words, the clock starts running regardless of whether “discovery” is actually achieved. And “there is no exception [to this rule] under Texas law for those who make a diligent inquiry but fail to obtain a positive diagnosis.” *Id.* How much less so could there be an exception for those such as Plaintiff who make no inquiry at all.

The uncontroverted facts here demonstrate that Plaintiff had knowledge of facts that would cause a reasonable person to investigate and determine her legal rights. Plaintiff testified that she and her husband “had a very active sex life” before her implantation on November 20, 2009. (2/14 Rough Tr. (“RT”) 41:9-12, 69:20-22). Dr. Boreham instructed her not to engage in sexual intercourse for six weeks. (2/14 RT 41:2-8). Plaintiff followed those instructions and then went back to see Dr. Boreham for her six-week follow-up appointment on January 27, 2010, at which time Dr. Boreham told Plaintiff she was “healing” and was “good to go.” (2/14 RT 41:16-24, 69:23-70:4). Critically, Dr. Boreham also told Plaintiff to return if she had “any problems.” (2/14 RT 70:15-18). Plaintiff and her husband attempted sex that very night, but she

testified that she found it too painful. (2/14 RT 42:3-8). They waited “three or four weeks later” to try again, but Plaintiff says she again experienced pain. (2/14 RT 42:10-11).

Despite being instructed to refrain from sex for only six weeks, being told at six weeks that she was “good to go” – and, most importantly, to return if she experienced “any problems” – Plaintiff never did go back to see Dr. Boreham, nor sought treatment for her dyspareunia from any other healthcare provider at that time. (2/14 RT 41:13-24, 70:15-25, 71:8-23). She did not seek medical attention or advice even after seeing, in “late 2010,” a lawyer advertisement listing supposed complications of mesh slings such as “[p]ain with sex,” a “few months” after which she contacted an attorney. (2/14 RT 50:10-51:13, 51:21-52:1, 79:2-22). Indeed, she did not do so until around nine months after filing suit on July 25, 2012, when she visited Dr. Zimmern in April 2013. (2/14 RT 71:4-7, 71:13-16, 79:19-22).

The alleged persistence of Plaintiff’s painful sex well after Dr. Boreham told Plaintiff that she was “good to go,” along with Dr. Boreham’s instruction to return if she had “any problems,” together would have caused a reasonable person to diligently investigate and determine her legal rights. Plaintiff was well aware of the nature of her injury within months of her November 20, 2009 surgery and January 27, 2010 post-operative visit, yet it was not until nearly two years and six months after the post-operative visit, on July 25, 2012, that she filed this lawsuit.

Plaintiff says she put the pieces together following a lawyer advertisement she saw in “late 2010” regarding “[p]ain with sex.” (2/14 RT 51:12, 79:1-8). But that advertisement actually demonstrates that her claim is untimely: it conveyed neither any new information to Plaintiff nor connected any dots for her. Plaintiff already knew she had an active sex life before the implantation; she already knew she was to refrain from sex for only six weeks; she already knew Dr. Boreham told her at six weeks that she was “good to go”; she already knew she

continued to experience pain with sex, which she attributed to the TVT implantation, at six weeks after implantation and again three or four weeks later; and she already knew Dr. Boreham told her she should come back if she had “any problems.” All this information and connections were just as within Plaintiff’s grasp in January or February 2010 as they were in late 2010. Plaintiff’s cause of action thus accrued no later than January or February 2010, several months before July 25, 2010.

This case bears a striking resemblance to the circumstances in *Timberlake v. A.H. Robins Co., Inc.*, 727 F.2d 1363 (5th Cir. 1984). There, the plaintiff wore an Dalkon Shield IUD and began experiencing pain and fever in March 1978. She went to her doctor who removed the IUD, but her symptoms worsened and in April 1978 she was diagnosed with acute pelvic inflammatory disease and underwent a hysterectomy. Not until “the time [she] was told that she would have to have th[at] surgery and after it was performed,” i.e., April 1978, did her doctor inform her “that her problems had been caused by the” IUD. *Id.* at 1364. Yet she did not file suit until 1981, shortly after seeing a television program concerning the device. Applying Texas law, the Fifth Circuit concluded that plaintiff’s claim was untimely because it accrued at the time of her pain and fever in March and not the doctor’s diagnosis and causal assessment in April:

Timberlake knew of her injury and its cause in March, 1978. At that point, the statute of limitations was triggered and she had two years in which to investigate any possible wrongdoing by Robins. Her failure to institute this action within the two-year period bars her from proceeding on the theories of negligence and tort.

Id. at 1366; *see also Porterfield*, 183 F.3d at 466-67 (claims time-barred where mesh implant plaintiff attributed problems such as pain and tenderness to the mesh a week or two after surgery, but did not file suit until two years and nine months after implantation, because plaintiff was “aware of the nature of her injury soon after her first surgery” to implant the mesh).

III. Ethicon Is Entitled to Judgment on Plaintiff's Claim for Punitive Damages.

The Court need not address Plaintiff's request for punitive damages because her substantive claim fails. That aside, punitive damages may be awarded only "if the plaintiff proves, by clear and convincing evidence, that the harm suffered was the result of the defendant's acts or omissions, and such acts or omissions were actuated by actual malice or accompanied by a wanton and willful disregard of persons who foreseeably might be harmed by those acts or omissions." N.J.S.A. § 2A:15-5.12. Plaintiff's burden of proof may not be satisfied by proof of any degree of negligence, including gross negligence. N.J.S.A. § 2A:15-5.12(a). Plaintiff has not satisfied this standard.

No evidence in this trial revealed the requisite malice or wanton and willful disregard of safety. As explained in Ethicon's trial brief [Doc. 286 at 2-3], Plaintiff can show, at best, merely her paid experts' disagreement with the vast majority of the medical and scientific communities. But "[a]n award of punitive damages is not appropriate when room exists for reasonable disagreement over the relative risks and utilities of the conduct at issue." *Burke v. Deere & Co.*, 6 F.3d 497, 511 (8th Cir. 1993); *see also Satcher v. Honda Motor Co.*, 52 F.3d 1311, 1317 (5th Cir. 1995); *Plasencia v. Orgill, Inc.*, 2012 U.S. Dist. LEXIS 32326 (D.N.J. Mar. 9, 2012) (New Jersey law) (expert report failed to support award of punitive damages). Given the resounding support for the TVT among the physicians who treat stress urinary incontinence, the reasonableness of any disagreement over its safety cannot seriously be challenged. Indeed, the evidence shows that, at all times, Ethicon acted in good faith to develop a product to help women suffering from stress urinary incontinence.

For all these reasons, the record lacks clear and convincing evidence that Ethicon's design of the TVT was prompted by actual malice or accompanied by a willful and wanton disregard of foreseeable harm to Plaintiff.⁴

IV. Plaintiff's Claims Are Preempted Insofar as They Are Based on the Use of PROLENE Polypropylene Filaments.

To preserve its objection,⁵ Ethicon respectfully submits that Plaintiff's design defect claim is preempted to the extent that it is based on the use of PROLENE, in light of the FDA's approval of the PROLENE suture filament comprising the TVT device. As explained more fully in Ethicon's Motion for Partial Summary Judgment [Doc. 129], the PROLENE suture filament has been regulated as an approved drug and, subsequently, a Class III device. *See* 21 U.S.C. § 360j(1)(1). The FDA's regulation of PROLENE sutures as a drug and Class III device resulted in requirements with respect to safety and effectiveness, and so Plaintiff's claim is preempted to the extent it is based on TVT's use of PROLENE. *See Riegel*, 552 U.S. at 322-33; 21 U.S.C. § 360k. Moreover, the evidence at trial confirms that the PROLENE mesh used in the TVT is made of the same material as the PROLENE suture. (Hart 676:24-677:7).

V. Plaintiff's Claims Do Not Survive the Presumptions of Non-liability to Which Ethicon Is Entitled and Which Plaintiff Cannot Rebut.

To preserve its objections,⁶ Ethicon submits that Plaintiff's claims are barred by TEX. CIV. PRAC. & REM. CODE ANN. §§ 82.007, 82.008(a), and 82.008(c). This argument is

⁴ Ethicon acknowledges that the Court denied Ethicon's and granted Plaintiff's motion for summary judgment as to the threshold question of whether Ethicon is immune from punitive damages under New Jersey law. [Doc. 194]. To preserve its objections, and for the reasons stated in its summary judgment papers [Doc. 131], Ethicon respectfully submits that punitive damages are barred by the New Jersey Products Liability Act on the ground that the TVT device falls within the scope of the punitive damages bar of N.J.S.A. § 2A:58C-5.

⁵ The Court denied Defendants' request for partial summary judgment on preemption on January 15, 2014 [Doc. 196].

⁶ The Court granted Plaintiff's motion for summary judgment on these defenses on January 15, 2014. [Doc. 196].

explained more fully in Ethicon's Opposition to Plaintiff's Motion for Summary Judgment [Doc. 183]. Because TVT is subject to two sets of mandatory federal safety standards and regulations governing each of the characteristics on which Plaintiff bases her claims, has complied with the same, and because the FDA approved the use of the PROLENE filaments comprising the TVT, the presumptions of these statutes are applicable and have not been rebutted.

CONCLUSION

For the foregoing reasons, Ethicon respectfully requests that the Court enter judgment in its favor.

Dated: February 18, 2014

Respectfully submitted,

/s/ Christy D. Jones

Christy D. Jones
Butler Snow LLP
1020 Highland Colony Parkway
Suite 1400 (39157)
P.O. Box 6010
Ridgeland, MS 39158-6010
(601) 985-4523
christy.jones@butlersnow.com

/s/ David B. Thomas

David B. Thomas (W.Va. Bar #3731)
Thomas Combs & Spann PLLC
300 Summers Street
Suite 1380 (25301)
P.O. Box 3824
Charleston, WV 25338
(304) 414-1807
dthomas@tcspllc.com

COUNSEL FOR DEFENDANTS
ETHICON, INC. AND
JOHNSON & JOHNSON

CERTIFICATE OF SERVICE

I certify that on February 18, 2014, I electronically filed this document with the Clerk of the Court using the CM/ECF system which will send notification of this filing to CM/ECF participants registered to receive service in this case.

/s/ Christy D. Jones

Christy D. Jones